510(K) SUMMARY

Corentec Co., Ltd.

BENCOX® Bipolar Cup System

July 13, 2011

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BENCOX Bipolar Cup System
Common Name:	Total Hip Prosthesis System
Classification Regulations:	21 CFR 888.3358, 888.3390
Class	II
Product Codes:	LPH, KWY
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The Bencox Bipolar Cup system is intended for cementless use in partial or total hip arthroplasty in primary or revision surgery for the following conditions:
a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis;
b. Inflammatory degenerative joint disease, such as rheumatoid arthritis;

c. Treatment of non-union, femoral neck fracture and trochantric fractures of the proximal femur with head involvement, unmanageable using other techniques;
d. Patients with failed previous surgery where pain, deformity, or dysfunction persists;
e. Revision of previously failed hip arthroplasty.

DEVICE DESCRIPTION

The BENCOX Bipolar Cup System is a cementless, metal-on-polyethylene bearing hip system for hip arthroplasty. It consists of components, Femoral stem – BENCOX ID Stem; Femoral head – BENCOX Metal Head; Acetabular system – BENCOX Bipolar Cup (Shell; Insert; Lock Ring & PE ring) and BENCOX Hip Instrumentation.

The Bencox ID Stem is manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* and has a proven titanium plasma spray coating with pure titanium conforming to ASTM F1580-07, *Standard Specification for Titanium and Ti-6 Al-4 V Alloy Powders for Coatings of Surgical Implants* with about two decades of clinical experience

Bencox Metal Head components are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F1537, *Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).*

The BENCOX Bipolar Cups are provided as the preassembled cup (CoCr shell + PE Liner) and PE ring is assembled by the user (surgeon). The shell is made of Cobalt-chromium-molybdenum alloy conforming to ASTM F75-07, *Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants.* The PE liner and locking ring is made of Ultra-high molecular weight polyethylene conforming to ASTM F648 *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.*

Bencox Bipolar Cup System components are sterilized by gamma irradiation.

EQUIVALENCE TO MARKETED DEVICES

Corentec Co., Ltd. submits the following information in this Premarket Notification to demonstrate that for the purposes of FDA's regulation of medical devices, the BENCOX Bipolar Cup System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Biomet, Inc., Taperloc® 12/14 Taper Femoral Components cleared under K043537;
Biomet, Inc., Malloy Head® Lateralized Press-Fit Femoral cleared under K003429;
Corin Group Ltd., Tri-Fit® Femoral Stem cleared under K010243;
Biomet, Inc., Metal On Metal Acetabular System cleared under K993438;
Biomet, Inc., M^2a®32mm Taper System cleared under K003363;
StelKast Inc., Stelkast Bipolar Head cleared under K972961;
Biomet, Inc., RingLoc® Bi-Polar Acetabular Component cleared under K051569;
Stryker (Osteonics Corp.), UHR Universal hip Replacement cleared under K800207;

The Bencox Bipolar Cup System's Bencox ID Stem and the Taperloc Stem (K043537), Mallory Head (K003429) and the TriFit (K010243) are made of the same material and have the same titanium plasma spray coating. Bencox ID Stem & TriFit (K010243) has the same neck angle. All the stems have a similar overall geometries and ranges of sizes.

The Bencox Bipolar Cup System's Bencox Metal Head and the Metal on Metal Acetabular System (K993438) and M2a™ 32 mm Acetabular System (K003363) all include modular femoral heads made of the same material and a similar tapered interface to the femoral stem. The subject and predicate modular femoral heads all encompass a similar range of head sizes, neck lengths and femoral offsets, and all have similar surface finish and sphericity.

The Bencox Bipolar Cup System's Bencox Bipolar Cup and StelKast (K972961), Ringloc Bi-polar (K051569) and UHR (K800207), all the shell is made with a highly polished Cobalt Chrome alloy (CoCrMo) shell and a polyethylene (UHMWPE) liner with an integrated or separate polyethylene femoral head lock ring. Bencox Bipolar Cup has a liner locking mechanism similar to Ringloc Bi-polar (K051569) using a titanium lock ring. Bencox Bipolar Cup has a femoral head lock ring similar to StelKast (K972961).All the devices are self-centering with positive eccentricity. The devices are offered to fit either 22 mm and/or 28 mm femoral heads. All the bipolar cups shell has a similar range of sizes.

Performance testing was performed to demonstrate substantial equivalence and included methods described in the following standards: ISO 7206-4, ISO 7206-9, ISO 7206-10, ISO 14242-1, ISO 14242-2, ASTM F1147, ASTM F1044, ASTM F1160, ASTM F1978, ASTM F1875, ASTM 2582 and ASTM F1820.

K112019 (pg. 4 of 4)

Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy of the bipolar cup system components for its intended use.

Overall, the BENCOX Bipolar Cup System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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OCT 12 2011

Re: K112019
Trade/Device Name: BENCOX Bipolar Cup System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY, LPH
Dated: July 13, 2011
Received: July 14, 2011

Dear Mr. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112019

INDICATIONS FOR USE

510(k) Number (if known): K112019

Device Name: BENCOX Bipolar Cup System

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e. Revision of previously failed hip arthroplasty

Prescription Use: X AND / OR Over-The Counter Use: ———
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112019